HLA-B*42 Product Insert Page 1 of 20

101.543-06u - without *Taq* polymerase

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.: 62K Lot-specific information www.olerup-ssp.com

Olerup SSP® HLA-B*42

Product number: 101.543-06u – without *Taq* polymerase

Lot number: 62K

Expiry date: 2013-April-01

Number of tests: 6 Number of wells per test: 15

Storage - pre-aliquoted primers: dark at -20°C

PCR Master Mix: -20°C
 Adhesive PCR seals
 Product Insert

This Product Description is only valid for Lot No. 62K.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-B*42 Lot.

The HLA-B*42 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup* SSP® HLA-B*42 lot was made (Lot No. 96F).

Four wells have been added to the HLA-B*42 kit, wells **12 to 15**.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

| Well | 5'-primer | 3'-primer | rationale |
|------|-----------|-----------|---|
| 10 | - | - | Exchanged positive control primer pair. |
| 12 | New | New | New primer pair for the HLA-B*42:11 allele. |
| 13 | New | New | New primer pair for the HLA-B*42:12 allele. |
| 14 | New | New | New primer pair for the HLA-B*42:13 allele. |
| 15 | New | New | New primer pair for the HLA-B*42:14 allele. |

101.543-06u - without Taq polymerase

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.: 62K Lot-specific information www.olerup-ssp.com

PRODUCT DESCRIPTION

HLA-B*42 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*42:01 to B*42:14 alleles.

PLATE LAYOUT

Each HLA-B*42 test consists of 15 PCR reactions in a 16 well cut PCR plate. Well 16 is empty.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|----|----|----|----|----|----|-------|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | empty |

The 16 well PCR plate is marked with 'HLA-B*42' in silver/gray ink.

Well No. 1 is marked with the Lot No. '62K'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 16 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*42 SSP subtypings will be influenced by most B*07, most B*08, the B*13:14, six B*14, several B*15, the B*18, six B*27, six B*35, the B*37, the B*38, the B*39, several B*40, the B*41, many B*44, the B*45, the B*48, five B*51, two B*52, two B*53, most B*54, many B*55, most B*56, two B*57, two B*67, the B*81, the B*82 and the B*83:01 alleles when present on the other haplotype. In addition, the C*07:04:01-07:04:04, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142 and C*15:25 alleles will be amplified by primer mixes 7 and 10, and the C*07:68 allele will be amplified by primer mix 10.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*42, i.e. **B*42:01 to B*42:14**, recognized by the HLA Nomenclature Committee in July 2010¹ will be amplified by the primers in the HLA-B*42 SSP kit. The HLA-B*42 subtyping kit cannot distinguish the B*42:01:01 and 42:01:02 or the 42:05:01 and 42:05:02 alleles.

¹HLA-B alleles listed on the IMGT/HLA web page 2010-July-16, release 3.1.0, www.ebi.ac.uk/imgt/hla.

Lot No.: 62K Lot-specific information www.olerup-ssp.com

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 15 alleles generate 13 amplification patterns that can be combined in 91 homozygous and heterozygous combinations. 38 of these genotypes do not give rise to unique amplification patterns.

```
++++-+-- +-----
                        *42:02, *42:04 = *42:04, *42:09
+++-++-- +-----
                        *42:02, *42:05:01 = *42:05:01, *42:09
+++--++- +-----
                        *42:02, *42:06 = *42:06, *42:09
+++--+-- ++----
                        *42:02, *42:08 = *42:08, *42:09
+++--+-- +-+---
                        *42:02, *42:10 = *42:09, *42:10
+++--+-- +---+--
                        *42:02, *42:12 = *42:09, *42:12
+++--+- +---+-
                        *42:02, *42:13 = *42:09, *42:13
+++--+- +---+
                        *42:02, *42:14 = *42:09, *42:14
+++--+-- +-----
                        *42:01:01, *42:02 = *42:01:01, *42:09
++--+-- +----
                        *42:01:01, *42:05:01 = *42:05:01, *42:05:01
++---+
                        *42:01:01, *42:06 = *42:06, *42:06
++---+-- ++-----
                        *42:01:01, *42:08 = *42:08, *42:08
++---+-- +-+---
                        *42:01:01, *42:10 = *42:10, *42:10
++---+--
                        *42:01:01, *42:12 = *42:12, *42:12
++---+
                        *42:01:01, *42:14 = *42:14, *42:14
-++--+- +--+--
                        *42:02, *42:11 = *42:09, *42:11
-++--+- +-----
                        *42:02, *42:07 = *42:07, *42:09
-++--+-- +-----
                        *42:02, *42:02 = *42:02, *42:09
-+--+ ---+
                        *42:07, *42:11 = *42:11, *42:11
```

42:01:01 = 42:01:01 and 42:01:02 42:05:01 = 42:05:01 and 42:05:02

Lot No.: 62K Lot-specific information www.olerup-ssp.com

SPECIFICITY TABLE

HLA-B*42 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-B*42 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-B*42 alleles | Other amplified HLA-B alleles ³ |
|---------------------|--|-----------------------------------|---|--|
| 1 | 215 bp | 800 bp | *42:01:01- 42:01:02, 42:04-42:06, 42:08, 42:10, 42:12-42:14 | *07:02:01-07:02:20, 07:04-07:07, 07:09, 07:11-07:12, 07:14-07:15, 07:17-07:26, 07:28, 07:30-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:68:02, 07:70, 07:72-07:82, 07:84, 07:86-07:115, 15:76, 15:101, 35:76, 44:90, 54:01, 54:03-54:06, 54:08N-54:23, 55:01:01-55:05, 55:07-55:15, 55:17, 55:19-55:24, 55:26-55:33, 55:35-55:43, 56:01:01-56:07, 56:09-56:13, 56:15-56:16, 56:18-56:22, 56:24-56:29, 67:01:01-67:01:02, 81:01-81:04N, 82:01-82:03, 83:01 |
| 2 | 215 bp | 1070 bp | *42:01:01- 42:02, 42:05:01- 42:12, 42:14 | *07:04, 07:19, 07:25, 08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:59, 08:61-08:62, 35:87, 37:09, 41:02:01-41:02:02, 41:04, 41:10-41:11, 44:106 |
| 3 ⁵ 4 | 215 bp 220 bp | 1070 bp 1070 bp | *42:02, 42:09 *42:04 | *45:06, 54:02, 55:16 *08:09, 15:83, 41:01, 41:05- 41:07, 41:09, 41:12, 44:15, 44:18, 44:20, 44:100, 45:01-45:12, 51:08, 51:20, 51:36, 51:44N, |
| 5 ⁴ | 105 bp | 800 bp | *42:05:01- 42:05:02 | 52:19, 55:20, 56:13 *07:04, 07:25, 40:136, 41:08 |
| 6 | 165 bp | 1070 bp | *42:01:01- 42:02, 42:04- 42:08, 42:10- 42:14 | *08:01:01-08:05, 08:08N- 08:12:03, 08:15-08:19N, 08:21- 08:24, 08:26-08:27, 08:29-08:36, 08:38-08:39, 08:41-08:48, 08:50- 08:54, 08:56-08:62, 15:83, 35:87, 37:12, 40:136, 41:01-41:03:02, |

| | | | | ###.olcrup 35p.00m |
|-----------------------|--------|---------|--|---|
| 7 | 160 bp | 1070 bp | *42:06 | 41:05-41:09, 41:11-41:12, 44:14, 44:62, 51:08, 51:20, 51:36, 51:44N, 52:19, 55:20, 56:13, 57:09, 82:01-82:03 *08:49, 37:01:01-37:01:07, 37:03N-37:06, 37:08, 37:10-37:11, 37:13-37:23, 44:15, 44:18, 45:01-45:02, 45:04-45:08, 45:10-45:12, 56:13, 82:01-82:03, C*07:04:01**-07:04:04**, C*07:11**-07:12**, C*07:45**, C*07:63**, C*07:101**, C*07:139**, C*07:142**, C*15:25 |
| 8 ⁶ | 215 bp | 1070 bp | *42:07, 42:11 | *07:03, 07:08, 07:16, 07:27, 07:32, 07:38, 07:50, 07:69, 07:85, 13:14, 14:01, 14:07N-14:08, 14:10, 14:12, 14:14, 15:68, 15:71, 15:175, 18:01:01-18:03, 18:05-18:15, 18:17N-18:24, 18:26-18:50, 27:12, 27:16, 27:18, 27:23, 27:29, 35:50, 35:84, 37:01:01-37:23, 38:01:01-38:04, 38:06-38:23, 39:01:01:01-39:01:01:02L, 39:01:03-39:03, 39:05:01-39:11, 39:13:01-39:20, 39:22-39:51, 39:53-39:60, 40:02:01-40:06:03, 40:08-40:09, 40:11:01-40:11:02, 40:13, 40:18-40:20, 40:24, 40:26-40:29, 40:35, 40:37, 40:39-40:40, 40:44, 40:50, 40:56, 40:64, 40:68, 40:70-40:71, 40:74-40:75, 40:78, 40:82-40:83, 40:85-40:86, 40:89-40:91, 40:93-40:99, 40:104-40:105, 40:107, 40:109, 40:111, 40:115, 40:119-40:120, 40:122, 40:127, 40:131, 40:133Q, 40:142N-40:145, 44:103, 48:01:01-48:21, 48:23, 51:57, 53:21 |
| 9 | 170 bp | 1070 bp | *42:01:01- 42:02, 42:04- 42:06, 42:08- 42:10, 42:12- 42:14 | *07:02:01-07:02:20, 07:04-07:07, 07:09, 07:11-07:12, 07:14-07:15, 07:17-07:26, 07:28-07:31, 07:33-07:36, 07:39-07:49N, 07:51-07:55, 07:57-07:64, 07:66-07:68:02, 07:70-07:71, 07:73-07:82, 07:84, 07:86-07:115, |

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

| | | | • | <u> </u> |
|-------------------|--------|---------|--------|---|
| | | | | 54:21, 55:10, 56:16, 67:01:01-67:01:02, 81:01-81:04N, 82:01-82:03, 83:01 |
| 10 ^{4,5} | 105 bp | 1070 bp | *42:08 | *07:19, 15:51, 15:83, 15:179, 15:199, 27:47, 35:38, 35:115, 37:01:01-37:01:07, 37:03N-37:04:01, 37:05-37:06, 37:08-37:23, 41:09, 44:05:01-44:06, 44:08-44:09, 44:11-44:12, 44:14-44:25, 44:27, 44:33-44:34, 44:41-44:42, 44:44, 44:48-44:49, 44:51-44:53, 44:55, 44:58, 44:66-44:68, 44:70, 44:72-44:75, 44:74, 44:93, 44:93, 44:95, 44:97, 44:99-44:102, 44:104, 44:106, 45:01-45:04, 45:06-45:12, 51:08, 51:20, 51:36, 51:44N, 52:19, 53:22, 56:13, 57:09, 57:24, 82:01-82:03, 83:01, C*07:04:01-07:04:04, C*07:11-07:12, C*07:45, C*07:63, C*07:142, C*15:25 |
| 11 | 180 bp | 1070 bp | *42:10 | *08:49, 53:15 |
| 12 ⁴ | 105 bp | 1070 bp | *42:11 | *07:27, 07:50, 08:04, 08:17, 08:54, 15:03:01-15:03:03, 15:47, 15:54, 15:61-15:62, 15:64, 15:68-15:69, 15:91, 15:98, 15:103, 15:123, 15:127, 15:131-15:132, 15:151, 15:156, 15:158, 15:173, 18:37, 27:18, 27:29, 38:03, 39:02:01-39:02:02, 39:08, 39:13:01-39:13:02, 39:23, 39:39, 39:49, 40:12, 40:46, 40:93, 44:40, 44:44, 48:01:01-48:05, 48:07-48:23, 52:16, 55:18 |
| 13 ⁴ | 65 bp | 1070 bp | *42:12 | ·, · · · · · · · · |
| 14 | 290 bp | 1070 bp | *42:13 | *08:49, 08:60, 53:15 |
| 15 | 230 bp | 1070 bp | *42:14 | *41:06 |

Lot No.: 62K Lot-specific information www.olerup-ssp.com

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*42 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*42 subtyping.

In addition, well number 5 contains the primer pair giving rise to the shorter, 800 bp, internal

positive control band in order to allow kit identification.

³Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B*42 alleles will be amplified by primer mixes 1 to 12, 14 and 15. In addition, the C*07:04:01-07:04:04, C*07:11-07:12, C*07:45, C*07:63, C*07:101, C*07:139, C*07:142 and C*15:25 alleles will be amplified by primer mixes 7 and 10, and the C*07:68 allele will be amplified by primer mix 10.

⁴Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.

⁵Primer mixes 3 and 10 may give rise to nonspecific amplifications.

⁶Primer mix 8 may give a lower yield of specific PCR product than the other HLA-B*42 primer

'w', might be weakly amplified.

| INTERF | PRET | ATION | ITAB | LE | | | | |
|---|----------------------------------|----------------------------------|-------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--------------------|
| HLA-B | *42 S | SP su | btypir | ng | | | | |
| Amplification patte | rns of t | the B*4 | 2:01 to | 42:14 | alleles | | | |
| | | | | W | ell ell | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Length of spec. | 215 | 215 | 215 | 220 | 105 | 165 | 160 | 215 |
| PCR product | | | | | | | | |
| Length of int. | 800 | 1070 | 1070 | 1070 | 800 | 1070 | 1070 | 1070 |
| pos. control ¹ | | | | | | | | |
| 5'-primer ² | 97 | 363 | 97 | 357 | 540 | 412 | 419 | 103 |
| | 5' -TCT 3' | ^{5'} -AgC ^{3'} | 5' -TCC 3' | ^{5'} -Tgg ^{3'} | ^{5'} -gAC ^{3'} | ^{5'} -ATA ^{3'} | ^{5'} -gTT ^{3'} | 5' -CCT |
| | | | | | | | 419 | 103 |
| | | | | | | | ^{5'} -gTT ^{3'} | ^{5'} -CCT |
| | | | | | | | | |
| 3'-primer ³ | 272 | 538 | 272 | 538 | 605 | 538 | 538 | 277 |
| | ^{5'} -TgT ^{3'} | ^{5'} -gTC ^{3'} | | ^{5'} -gTC ^{3'} | - | ^{5'} -gTC ^{3'} | ^{5'} -gTC ^{3'} | ⁵' -ggT |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| HLA-B allele ⁴ | | | | | | | | |
| *42:01:01-42:01:02 | 1 | 2 | | | | 6 | | |
| *42:02 | | 2 | 3 | | | 6 | | |
| *42:04 | 1 | | | 4 | | 6 | | |
| *42:05:01-42:05:02 | 1 | 2 | | | 5 | 6 | | |
| *42:06 | 1 | 2 | | | | 6 | 7 | |
| *42:07 | | 2 | | | | 6 | | 8 |
| *42:08 | 1 | 2 | | | | 6 | | |
| *42:09 | | 2 | 3 | | | | | |
| *42:10 | 1 | 2 | | | | 6 | | |
| *42:11 | | 2 | | | | 6 | | 8 |
| *42:12 | 1 | 2 | | | | 6 | | |
| *42:13 | 1 | | | | | 6 | | |
| *42:14 | 1 | 2 | | | | 6 | | |
| *07:02:01-07:02:20, 07:05:01-07:07, | | | | | | | | |
| 07:09, 07:11-07:12, 07:14-07:15, 07:17- | | | | | | | | |
| 07:18:02, 07:20-07:24, 07:26, 07:28, | | | | | | | | |
| 07:30-07:31, 07:33-07:36, 07:39- | | | | | | | | |
| 07:49N, 07:51-07:55, 07:57-07:64, | 1 | | | | | | | |
| 07:66-07:68:02, 07:70, 07:73-07:82, | | | | | | | | |
| 07:84, 07:86-07:115, 54:21, 55:10, | | | | | | | | |
| 56:16, 67:01:01-67:01:02, 81:01- | | | | | | | | |
| 81:04N | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

| | | | | INTER | RPRE | TATIO | ON TABLE |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|------------|----------------------------------|----------------------------------|---|
| | | | • | | | | subtyping |
| | | An | nplificat | | | | 3*42:01 to 42:14 alleles |
| | | 7 111 | Well | о ра | | <u> </u> | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | |
| 170 | 105 | 180 | 105 | 65 | 290 | 230 | Length of spec. |
| | | 100 | | | | | PCR product |
| 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | Length of int. |
| | | | | | | | pos. control ¹ |
| 142 | 540 | 463 | 206 | 540 | 355 | 412 | 5'-primer ² |
| | | | 5' -AgA 3' | | | | 5 -primer |
| | gAO | igh | AgA | gAG | TOA | AIA | |
| | | | | | | | |
| 272 | 603 | 603 | 272 | 566 | 603 | 603 | 3'-primer ³ |
| ^{5'} -TgT ^{3'} | ^{5'} -gTC ^{3'} | ^{5'} -gTg ^{3'} | ^{5'} -Tgg ^{3'} | 5' -CCC 3' | ^{5'} -gTg ^{3'} | ^{5'} -gTg ^{3'} | - I |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | HLA-B allele ⁴ |
| 9 | | | | | | | *42:01:01-42:01:02 |
| 9 | | | | | | | *42:02 |
| 9 | | | | | | | *42:04 |
| 9 | | | | | | | *42:05:01-42:05:02 |
| 9 | | | | | | | *42:06 |
| | | | | | | | *42:07 |
| 9 | 10 | | | | | | *42:08 |
| 9 | | | | | | | *42:09 |
| 9 | | 11 | | | | | *42:10 |
| | | | 12 | | | | *42:11 |
| 9 | | | | 13 | | | *42:12 |
| 9 | | | | | 14 | | *42:13 |
| 9 | | | | | | 15 | *42:14 |
| | | | | | | | *07:02:01-07:02:20, 07:05:01-07:07, |
| | | | | | | | 07:09, 07:11-07:12, 07:14-07:15, 07:17- |
| | | | | | | | 07:18:02, 07:20-07:24, 07:26, 07:28, |
| | | | | | | | 07:30-07:31, 07:33-07:36, 07:39- |
| 9 | | | | | | | 07:49N, 07:51-07:55, 07:57-07:64, |
| | | | | | | | 07:66-07:68:02, 07:70, 07:73-07:82, |
| | | | | | | | 07:84, 07:86-07:115, 54:21, 55:10, |
| | | | | | | | 56:16, 67:01:01-67:01:02, 81:01- |
| | | | | | | | 81:04N |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.: **62K**

Lot-specific information

www.olerup-ssp.com

| Length of spec. | 215 | 215 | 215 | 220 | 105 | 165 | 160 | 215 |
|--|-----|-----|-----|-----|-----|-----|-----|-----|
| PCR product | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *07:03, 07:08, 07:16, 07:32, 07:38, | | | | | | | | |
| 07:69, 07:85, 13:14, 14:01, 14:07N- | | | | | | | | |
| 14:08, 14:10, 14:12, 14:14, 15:71, | | | | | | | | |
| 15:175, 18:01:01-18:03, 18:05-18:15, | | | | | | | | |
| 18:17N-18:24, 18:26-18:36, 18:38- | | | | | | | | |
| 18:50, 27:12, 27:16, 27:23, 35:50, | | | | | | | | |
| 35:84, 37:02, 37:07, 38:01:01-38:02:02, | | | | | | | | |
| 38:04, 38:06-38:23, 39:01:01:01- | | | | | | | | |
| 39:01:01:02L, 39:01:03-39:01:11, | | | | | | | | |
| 39:03, 39:05:01-39:07, 39:09-39:11, | | | | | | | | |
| 39:14-39:20, 39:22, 39:24-39:38Q, | | | | | | | | |
| 39:40N-39:48, 39:50-39:51, 39:53- | | | | | | | | 8 |
| 39:60, 40:02:01-40:06:03, 40:08-40:09, | | | | | | | | |
| 40:11:01-40:11:02, 40:13, 40:18-40:20, | | | | | | | | |
| 40:24, 40:26-40:29, 40:35, 40:37, 40:39- | | | | | | | | |
| 40:40, 40:44, 40:50, 40:56, 40:64, | | | | | | | | |
| 40:68, 40:70-40:71, 40:74-40:75, 40:78, | | | | | | | | |
| 40:82-40:83, 40:85-40:86, 40:89-40:91, | | | | | | | | |
| 40:94-40:99, 40:104-40:105, 40:107, | | | | | | | | |
| 40:109, 40:111, 40:115, 40:119-40:120, | | | | | | | | |
| 40:122, 40:127, 40:131, 40:133Q, | | | | | | | | |
| 40:142N-40:145, 44:103, 48:06, 51:57, | | | | | | | | |
| 53:21 | | | | | | | | |
| *07:04, 07:25 | 1 | 2 | | | 5 | | | |
| *07:19 | 1 | 2 | | | | | | |
| *07:27, 07:50, 15:68, 18:37, 27:18, | | | | | | | | |
| 27:29, 38:03, 39:02:01-39:02:02, 39:08, | | | | | | | | |
| 39:13:01-39:13:02, 39:23, 39:39, 39:49, | | | | | | | | 8 |
| 40:93, 48:01:01-48:05, 48:07-48:21, | | | | | | | | |
| 48:23 | | | | | | | | |
| *07:29, 07:71 | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

| 170 | 105 | 180 | 105 | 65 | 290 | 230 | Length of spec. |
|-----|-----|-----|-----|----|-----|-----|--|
| | | | | | | | PCR product |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | *07:03, 07:08, 07:16, 07:32, 07:38, |
| | | | | | | | 07:69, 07:85, 13:14, 14:01, 14:07N- |
| | | | | | | | 14:08, 14:10, 14:12, 14:14, 15:71, |
| | | | | | | | 15:175, 18:01:01-18:03, 18:05-18:15, |
| | | | | | | | 18:17N-18:24, 18:26-18:36, 18:38- |
| | | | | | | | 18:50, 27:12, 27:16, 27:23, 35:50, |
| | | | | | | | 35:84, 37:02, 37:07, 38:01:01-38:02:02, |
| | | | | | | | 38:04, 38:06-38:23, 39:01:01:01- |
| | | | | | | | 39:01:01:02L, 39:01:03-39:01:11, |
| | | | | | | | 39:03, 39:05:01-39:07, 39:09-39:11, |
| | | | | | | | 39:14-39:20, 39:22, 39:24-39:38Q, |
| | | | | | | | 39:40N-39:48, 39:50-39:51, 39:53- |
| | | | | | | | 39:60, 40:02:01-40:06:03, 40:08-40:09, |
| | | | | | | | 40:11:01-40:11:02, 40:13, 40:18-40:20, |
| | | | | | | | 40:24, 40:26-40:29, 40:35, 40:37, 40:39- |
| | | | | | | | 40:40, 40:44, 40:50, 40:56, 40:64, |
| | | | | | | | 40:68, 40:70-40:71, 40:74-40:75, 40:78, |
| | | | | | | | 40:82-40:83, 40:85-40:86, 40:89-40:91, |
| | | | | | | | 40:94-40:99, 40:104-40:105, 40:107, |
| | | | | | | | 40:109, 40:111, 40:115, 40:119-40:120, |
| | | | | | | | 40:122, 40:127, 40:131, 40:133Q, |
| | | | | | | | 40:142N-40:145, 44:103, 48:06, 51:57, |
| | | | | | | | 53:21 |
| 9 | | | | | | | *07:04, 07:25 |
| 9 | 10 | | | | | | *07:19 |
| | | | | | | | *07:27, 07:50, 15:68, 18:37, 27:18, |
| | | | | | | | 27:29, 38:03, 39:02:01-39:02:02, 39:08, |
| | | | 12 | | | | 39:13:01-39:13:02, 39:23, 39:39, 39:49, |
| | | | | | | | 40:93, 48:01:01-48:05, 48:07-48:21, |
| | | | | | | | 48:23 |
| 9 | | | | | | | *07:29, 07:71 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |

Lot No.: **62K**

October 2010

Rev. No.: 00u

Lot-specific information

www.olerup-ssp.com

| [| Specific | | | I - | I - | • | • I - | _ |
|--|----------|-----|-----|-----|-----|-----|----------|-----|
| Length of spec. | 215 | 215 | 215 | 220 | 105 | 165 | 160 | 215 |
| PCR product | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *07:56, 07:65, 07:72, 15:76, 15:101, | | | | | | | | |
| 35:76, 54:01, 54:03-54:06, 54:08N- | | | | | | | | |
| 54:20, 54:22-54:23, 55:01:01-55:05, | | | | | | | | |
| 55:07-55:09, 55:11-55:15, 55:17, 55:19, | 1 | | | | | | | |
| 55:21-55:24, 55:26-55:33, 55:35-55:43, | | | | | | | | |
| 56:01:01-56:07, 56:09-56:12, 56:15, | | | | | | | | |
| 56:18-56:22, 56:24-56:29 | | | | | | | | |
| *08:01:01-08:03, 08:05, 08:08N, 08:10- | | | | | | | | |
| 08:11, 08:15, 08:18-08:19N, 08:21- | | | | | | | | |
| 08:24, 08:26-08:27, 08:29-08:36, 08:38- | | 2 | | | | 6 | | |
| 08:39, 08:41-08:48, 08:50-08:53, 08:56- | | | | | | 0 | | |
| 08:59, 08:61-08:62, 35:87, 41:02:01- | | | | | | | | |
| 41:02:02, 41:11 | | | | | | | | |
| *08:04, 08:17, 08:54 | | 2 | | | | 6 | | |
| *08:07, 08:14, 08:28, 08:37, 41:04, | | 2 | | | | | | |
| 41:10 | | | | | | | | |
| *08:09, 41:01, 41:05, 41:07, 41:12 | | | | 4 | | 6 | | |
| *08:12:01-08:12:03, 08:16, 41:03:01- | | | | | | _ | | |
| 41:03:02 | | | | | | 6 | | |
| *08:49 | | | | | | | 7 | |
| *08:60 | | | | | | 6 | | |
| *15:03:01-15:03:03, 15:47, 15:54, | | | | | | | | |
| 15:61-15:62, 15:64, 15:69, 15:91, | | | | | | | | |
| 15:98, 15:103, 15:123, 15:127, 15:131- | | | | | | | | |
| 15:132, 15:151, 15:156, 15:158, 15:173, | | | | | | | | |
| 40:12, 40:46, 44:40, 48:22, 52:16, 55:18 | | | | | | | | |
| *15:51, 15:179, 15:199, 27:47, 35:38, | | | | | | | | |
| 35:115, 44:02:01:01-44:02:13, | | | | | | | | |
| 44:05:01-44:06, 44:08-44:09, 44:11- | | | | | | | | |
| 44:12, 44:16-44:17, 44:19N, 44:21- | | | | | | | | |
| 44:25, 44:27, 44:33-44:34, 44:41-44:42, | | | | | | | | |
| 44:48-44:49, 44:51-44:53, 44:55, | | | | | | | | |
| 44:58N-44:59, 44:63, 44:66-44:68, | | | | | | | | |
| 44:70, 44:72-44:75, 44:78, 44:80, 44:83- | | | | | | | | |
| 44:84, 44:86-44:89, 44:91, 44:93, | | | | | | | | |
| 44:95, 44:97, 44:99, 44:101-44:102, | | | | | | | | |
| 44:104, 53:22, 57:24, <i>C*07:68</i> | | | | | | | | |
| *15:83, 41:09, 51:08, 51:20, 51:36, | | | | | | | | |
| 51:44N, 52:19 | | | | 4 | | 6 | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| | | | | | | | | |

| | | | | | | | · · |
|-----|-----|-----|-----|----|-----|-----|--|
| 170 | 105 | 180 | 105 | 65 | 290 | 230 | Length of spec. |
| | | | | | | | PCR product |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | *07:56, 07:65, 07:72, 15:76, 15:101, |
| | | | | | | | 35:76, 54:01, 54:03-54:06, 54:08N- |
| | | | | | | | 54:20, 54:22-54:23, 55:01:01-55:05, |
| | | | | | | | 55:07-55:09, 55:11-55:15, 55:17, 55:19, |
| | | | | | | | 55:21-55:24, 55:26-55:33, 55:35-55:43, |
| | | | | | | | 56:01:01-56:07, 56:09-56:12, 56:15, |
| | | | | | | | 56:18-56:22, 56:24-56:29 |
| | | | | | | | *08:01:01-08:03, 08:05, 08:08N, 08:10- |
| | | | | | | | 08:11, 08:15, 08:18-08:19N, 08:21- |
| | | | | | | | 08:24, 08:26-08:27, 08:29-08:36, 08:38- |
| | | | | | | | 08:39, 08:41-08:48, 08:50-08:53, 08:56- |
| | | | | | | | 08:59, 08:61-08:62, 35:87, 41:02:01- |
| | | | | | | | 41:02:02, 41:11 |
| | | | 12 | | | | *08:04, 08:17, 08:54 |
| | | | | | | | *08:07, 08:14, 08:28, 08:37, 41:04, |
| | | | | | | | 41:10 |
| | | | | | | | *08:09, 41:01, 41:05, 41:07, 41:12 |
| | | | | | | | *08:12:01-08:12:03, 08:16, 41:03:01- |
| | | | | | | | 41:03:02 |
| | | 11 | | | 14 | | *08:49 |
| | | | | | 14 | | *08:60 |
| | | | | | | | *15:03:01-15:03:03, 15:47, 15:54, |
| | | | | | | | 15:61-15:62, 15:64, 15:69, 15:91, |
| | | | 12 | | | | 15:98, 15:103, 15:123, 15:127, 15:131- |
| | | | | | | | 15:132, 15:151, 15:156, 15:158, 15:173, |
| | | | | | | | 40:12, 40:46, 44:40, 48:22, 52:16, 55:18 |
| | | | | | | | *15:51, 15:179, 15:199, 27:47, 35:38, |
| | | | | | | | 35:115, 44:02:01:01-44:02:13, |
| | | | | | | | 44:05:01-44:06, 44:08-44:09, 44:11- |
| | | | | | | | 44:12, 44:16-44:17, 44:19N, 44:21- |
| | | | | | | | 44:25, 44:27, 44:33-44:34, 44:41-44:42, |
| | 10 | | | | | | 44:48-44:49, 44:51-44:53, 44:55, |
| | | | | | | | 44:58N-44:59, 44:63, 44:66-44:68, |
| | | | | | | | 44:70, 44:72-44:75, 44:78, 44:80, 44:83- |
| | | | | | | | 44:84, 44:86-44:89, 44:91, 44:93, |
| | | | | | | | 44:95, 44:97, 44:99, 44:101-44:102, |
| | | | | | | | 44:104, 53:22, 57:24, <i>C*07:68</i> |
| | 40 | | | | | | *15:83, 41:09, 51:08, 51:20, 51:36, |
| | 10 | | | | | | 51:44N, 52:19 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | _ | _ | | _ | - | |

Lot No.: 62K

Lot-specific information

www.olerup-ssp.com

| Length of spec. | 215 | 215 | 215 | 220 | 105 | 165 | 160 | 215 |
|---|-----|-----|-----|-----|-----|-----|-----|-----|
| PCR product | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *37:01:01-37:01:07, 37:03N-37:04:01, | | | | | | | | |
| 37:05-37:06, 37:08, 37:10-37:11, 37:13- | | | | | | | 7 | 8 |
| 37:23 | | | | | | | | |
| *37:04:02 | | | | | | | 7 | 8 |
| *37:09 | | 2 | | | | | | 8 |
| *37:12 | | | | | | 6 | | 8 |
| *40:136, 41:08 | | | | | 5 | 6 | | |
| *41:06 | | | | 4 | | 6 | | |
| *44:14, 44:62, 57:09 | | | | | | 6 | | |
| *44:15, 44:18, 45:01-45:02, 45:04, | | | | 4 | | | 7 | |
| 45:07-45:08, 45:10-45:12 | | | | 4 | | | 1 | |
| *44:20, 44:100, 45:03, 45:09 | | | | 4 | | | | |
| *44:44 | | | | | | | | |
| *44:90 | 1 | | | | | | | |
| *44:106 | | 2 | | | | | | |
| *45:05 | | | | 4 | | | 7 | |
| *45:06 | | | 3 | 4 | | | 7 | |
| *53:15 | | | | | | | | |
| *54:02, 55:16 | | | 3 | | | | | |
| *55:20 | 1 | | | 4 | | 6 | | |
| *56:13 | 1 | | | 4 | | 6 | 7 | |
| *82:01-82:03 | 1 | | | | | 6 | 7 | |
| *83:01 | 1 | | | | | | | |
| C*07:04:01-07:04:04, C*07:11-07:12, | | | | | | | | |
| C*07:45, C*07:63, C*07:101, C*07:139, | | | | | | | w | |
| C*07:142 | | | | | | | | |
| C*15:25 | | | | | | | 7 | |
| HLA-B allele ⁴ | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*42 SSP subtyping.

In addition, well number 5 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

| 170 | 105 | 180 | 105 | 65 | 290 | 230 | Length of spec. |
|-----|-----|-----|-----|----|-----|-----|---|
| | | | | | | | PCR product |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | *37:01:01-37:01:07, 37:03N-37:04:01, |
| | 10 | | | | | | 37:05-37:06, 37:08, 37:10-37:11, 37:13- |
| | | | | | | | 37:23 |
| | | | | | | | *37:04:02 |
| | 10 | | | | | | *37:09 |
| | 10 | | | | | | *37:12 |
| | | | | | | | *40:136, 41:08 |
| | | | | | | 15 | *41:06 |
| | 10 | | | | | | *44:14, 44:62, 57:09 |
| | 40 | | | | | | *44:15, 44:18, 45:01-45:02, 45:04, |
| | 10 | | | | | | 45:07-45:08, 45:10-45:12 |
| | 10 | | | | | | *44:20, 44:100, 45:03, 45:09 |
| | 10 | | 12 | | | | *44:44 |
| | 10 | | | | | | *44:90 |
| | 10 | | | | | | *44:106 |
| | | | | | | | *45:05 |
| | 10 | | | | | | *45:06 |
| | | 11 | | | 14 | | *53:15 |
| | | | | | | | *54:02, 55:16 |
| | | | | | | | *55:20 |
| | 10 | | | | | | *56:13 |
| 9 | 10 | | | | | | *82:01-82:03 |
| 9 | 10 | | | | | | *83:01 |
| | | | | | | | C*07:04:01-07:04:04, C*07:11-07:12, |
| | 10 | | | | | | C*07:45, C*07:63, C*07:101, C*07:139, |
| | | | | | | | C*07:142 |
| | 10 | | | | | | C*15:25 |
| | | | | | | | HLA-B allele ⁴ |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |

 $^{^2}$ The nucleotide position, in the 2^{nd} or 3^{rd} exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence

of the 3 terminal nucleotides of the primer is given. 3 The nucleotide position, in the 2^{nd} or 3^{rd} exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

The B*4203 allele was never assigned.

^{&#}x27;w', might be weakly amplified.

| CELL LINE VALIDATION SHEET HLA-B*42 SSP primer set | | | | | | | | | | | | | | | | | | | |
|---|------|-----------------------------|------------------|---------------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|------------|-----------|-----------|-----------|-----------|-----------|----------|
| | | | HL | 4-B*42 | SS | ן א | orii | me | rs | et | | •• | | | | | | | |
| | | | | | _ | | _ | _ | _ | | | Ne | _ | 4.0 | | 4.0 | 4.0 | | 4 = |
| | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| | | | | .: | 9 | 302 | 903 | 90 | 305 | 900 | 207 | 808 | 600 | 310 | Ξ | 312 | 33 | 47 | 315 |
| | | | | ž | 909 | 909 | 909 | 909 | 909 | 909 | 909 | 909 | 909 | 783 | 909 | 783 | 783 | 783 | 783 |
| | | | | Prod. No. | 20096060 | 20096062 | 200960603 | 200960604 | 200960605 | 200960606 | 200960607 | 200960608 | 20096060 | 201078310 | 200960611 | 201078312 | 201078313 | 201078314 | 20107831 |
| | | | | | 2 | × | × | × | × | × | × | × | 2 | × | × | × | × | × | × |
| IHWC cell line | | B* | | | | | | | | | | | | | | | | | |
| 1 | 9001 | | *07:02 | *70.04 | + | - | - | - | - | - | - | - | + | - | - | - | - | - | _ |
| 3 | | LK707 E4181324 | *52:01 *52:01 | *73:01 | - | - | - | - | - | - | - | - | Ŀ | - | - | - | - | - | - |
| 4 | | GU373 | *15:10 | *53:01 | H | | - | - | - | | - | - | H | | - | | - | - | - |
| 5 | | KAS011 | *37:01 | 55.01 | H | | - | - | - | - | + | + | Н | + | - | | - | - | ÷ |
| 6 | 9353 | | *39:01 | *51:01 | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 7 | 9020 | | *18:01 | 01.01 | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 8 | 9025 | | *35:01 | | - | - | - | - | - | - | - | ÷ | - | - | - | - | - | - | - |
| 9 | 9026 | | *38:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *54:01 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | | PITOUT | *44:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *57:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9025 | JESTHOM | *27:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *15:01 | *15:20 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | | *40:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | | SWEIG007 | *40:02 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 17 | | CTM3953540 | *08:01 | *55:01 | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - |
| 18 | | 32367 | *14:01 | *56:01 | + | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 19 | | BM16 | *18:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 20 | | SLE005 | *40:01 | | - | - | - | - | • | - | - | - | - | - | - | - | - | - | - |
| 21 | | AMALA | *15:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | | KOSE | *35:03 | | - | - | - | - | - | - | - | - | ! - | - | - | - | - | - | - |
| 23 | 9124 | | *40:02 | *56:02 | + | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 24 | | JBUSH | *38:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 25 | | IBW9 | *14:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 26 27 | | WT49 CH1007 ¹ | *58:01 *07:05 | *51:01 | - | - | - | - | - | - | - | - | ١. | - | - | - | - | - | |
| 28 | | BEL5GB | *44:02 | *44:03 | + | - | - | - | - | | | - | + | + | - | | - | | - |
| 29 | 9050 | | *44:03 | 44.03 | Ε. | - | - | - | - | | - | - | H | Ξ. | - | - | - | - | - |
| 30 | 9021 | | *42:01 | | - | | - | - | - | - | - | | Ι. | - | - | - | - | - | - |
| 31 | | DUCAF | *18:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 32 | 9297 | | *41:02 | | - | + | - | - | - | + | - | ÷ | - | - | - | - | - | - | - |
| 33 | | MT14B | *40:01 | | - | | - | - | - | | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | | *38:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 35 | | SSTO | *44:02 | | - | - | - | - | - | - | - | - | - | + | - | - | - | - | - |
| 36 | | KT17 | *15:01 | *35:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | | HHKB | *07:02 | | + | - | - | - | - | - | - | - | + | - | - | - | - | - | - |
| 38 | 9099 | LZL | *15:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *08:01 | *27:05 | - | + | - | - | - | + | - | - | - | - | - | - | - | - | - |
| 40 | | WHONP199 | *13:02 | *46:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | | H0301 | *14:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | | TAB089 | *46:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | | T7526 | *46:01 | | - | - | - | - | - | - | - | - | <u> </u> | - | - | - | - | - | - |
| 44 | 9057 | | *38:01 | | - | - | - | - | - | - | - | + | - | - | - | - | - | - | - |
| 45 | | SHJO | *42:01 | *50:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 46 | | SCHU | *07:02 | | - | + | - | - | - | - | - | - | + | - | - | - | - | - | - |
| 47 | | TUBO ¹ | *51:01 | | - | - | - | - | - | - | - | - | - | + | - | - | - | - | - |
| 48 | 9303 | TER-ND | *35:01 | *44:03 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

¹The C*07:04 allele is amplified by primer mix 10 in the CH1007 and TUBO cell lines.



HLA-B*42 Product Insert Page 17 of 20

101.543-06u - without *Taq* polymerase

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.: 62K Lot-specific information www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*42 SSP

Product number: 101.543-06u – without *Taq* polymerase

Lot number: 62K

Expiry date: 2013-April-01

Number of tests: 6 Number of wells per test: 15

Well specifications:

| Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|
| 1 | 2009-606-01 | 9 | 2009-606-09 |
| 2 | 2009-606-02 | 10 | 2010-783-10 |
| 3 | 2009-606-03 | 11 | 2009-606-11 |
| 4 | 2009-606-04 | 12 | 2010-783-12 |
| 5 | 2009-606-05 | 13 | 2010-783-13 |
| 6 | 2009-606-06 | 14 | 2010-783-14 |
| 7 | 2009-606-07 | 15 | 2010-783-15 |
| 8 | 2009-606-08 | | |

The specificity of each primer solution of the HLA-B*42 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solution 5, 11 and 13 to 15 were available. The specificities of the primers in primer solution 5, 11 and 14 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solutions 13 and 15 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2010-October-29

Approved by:

Quality Control, Supervisor

HLA-B*42 Product Insert Page 18 of 20

101.543-06u - without *Taq* polymerase

General "Instructions for Use" IFU-02 Rev. No. 02 can be downloaded from

Lot No.: 62K Lot-specific information www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® HLA-B*42

Product number: 101.543-06u

Lot number: 62K

Intended use: HLA-B*42 high resolution histocompatibility testing

Manufacturer: Olerup SSP AB

Hasselstigen 1

SE-133 33 Saltsjöbaden, Sweden

Phone: +46-8-717 88 27 **Fax:** +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden 2010-October-29

Olle Olerup Managing Director HLA-B*42 Product Insert Page 19 of 20 101.543-06u – without *Taq* polymerase General "Instructions for Use"

IFU-02 Rev. No. 02 can be downloaded from

HLA-B*42 Product Insert Page 20 of 20 101.543-06u – without *Taq* polymerase General "Instructions for Use"

IFU-02 Rev. No. 02 can be downloaded from

Lot No.: 62K Lot-specific information www.olerup-ssp.com

ADDRESSES:

Manufacturer:

Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

Tel: +46-8-717 88 27 **Fax:** +46-8-717 88 18

E-mail: info-ssp@olerup.com

Web page: http://www.olerup-ssp.com

Distributed by:

Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.

Tel: +43-1-710 15 00 **Fax:** +43-1-710 15 00 10

E-mail: support-at@olerup.com **Web page:** http://www.olerup.com

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382

Tel: 1-877-OLERUP1 **Fax:** 610-344-7989

E-mail: info.us@olerup.com

Web page: http://www.olerup.com

For information on Olerup SSP distributors worldwide, contact Olerup GmbH.